Remarks

This paper is responsive to the Office Action mailed December 3, 2004, in connection with the above-identified patent application. In that Action, claims 1, 2, 6-11, 24, 25, 17, and 28 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,972,143 to Stevens. Claims 3 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens. Claim 4 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,147,315 to Weber. Lastly, claim 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of Weber and further in view of U.S. Patent No. 5,843,051 to Adams, et al.

THE NON-ART MATTERS

The drawings were objected to in the previous Office Action because, according to the Examiner, they do not include several reference sign(s) mentioned in the description. The drawings were objected to as failing to comply with 37 C.F.R. § 1.84(p)(5). The Examiner required a proposed drawing correction or corrected drawings because, according to him, they do not include reference sign(s) for: a first end; a second end; a first flexible outer coating; a second flexible outer coating; a first portion; a first transition area and a second portion. The Examiner further noticed that the same objections apply to the specification.

The Drawings are in Proper Form:

Applicant has tendered a proposed drawing correction to Figure 4b in a Request for Amendment to the Drawings filed on September 7, 2004. In that drawing correction, the first and second ends of the subject catheter are identified. The first and second flexible outer coatings have already been identified at reference numerals 58 and 62, respectively. The first portion of the catheter is identified in the drawing figures at reference numeral 74 and the second portion of the catheter is identified in the drawing figures at reference numeral 72. Reference numeral 73 has been added to identify the first transition area between the first and second portions of the catheter.

The Examiner did not comment on the drawings in the final Office Action mailed December 3, 2004. Accordingly, it is assumed that the drawing changes are acceptable and that the Examiner's earlier objections have been satisfied.

The Specification is in Proper Form:

Applicant has tendered an amendment on September 7, 2004 to page 14 of the specification to place it in better conformance with the drawing figures as amended.

It is respectfully submitted that no new matter has been added. More particularly, support is found for the changes to the specification tendered above in the specification and claims as originally filed and, particularly, beginning at page 4, line 19 and in the claims.

The Examiner did not comment on the specification in the final Office Action mailed December 3, 2004. Accordingly, it is assumed that the specification changes are acceptable and that the Examiner's earlier objections have been satisfied.

THE ART REJECTIONS

As noted above, claims 1, 2, 6-11, 24, 25, 17, and 28 were rejected as being anticipated by Stevens. Claims 3 and 26 were rejected as being unpatentable over Stevens. Claim 4 was rejected as being unpatentable over Stevens in view of Weber. Lastly, claim 5 was rejected as being unpatentable over Stevens in view of Adams, et al.

The Present Application:

For purposes of review, the subject application is directed to a reinforced catheter device including a coil reinforcement member carried on an inner tubular member, the coil reinforcement member being layered by first and second flexible outer coatings. The continuous coil reinforcement member is carried on the elongate flexible tubular member and extends from the proximal end of the catheter to the distal end of the catheter. First and second continuous flexible coatings cover

the coil reinforcement member and the tubular member in an overlapping fashion substantially entirely between the proximal end of the catheter and the distal end of the catheter. The outer coating is harder than the inner coating and is selectively removed over a length of the catheter to provide a thin flexible tip portion of the catheter. As described in the specification, the coil reinforcement member is disposed in the flexible tip portion as well as in the main body or proximal end of the catheter.

U.S. Patent No. 5,972,143 to Stevens:

U.S. Patent No. 5,972,143 to Stevens teaches a catheter including a coil reinforcement member covered in a practical sense by only a single flexible outer coating. In addition, the coil reinforcement member does not extend the entire length of the catheter but, however, is removed from a distal tip portion therein.

As described in the Stevens '143 patent, a braided overlay is adhered to an inner tubular member using a suitable bonding agent such as a UV curable epoxy coating. It is suggested at the top of column 7 of the '143 patent that a urethane or a nylon material can be used as a bonding agent.

After the reinforcement wire is braided onto the underlying tubular member, a thin secondary plastic coating is applied. It penetrates between the strands of wire braid and mechanically locks the stainless steel wires in place so that they do not unravel during a subsequent grinding operation intended to remove portions of the braided reinforcement wire along the length of the catheter. After the braid has been removed in selected areas (distal tip portion), the braided and non-braided continuous section of catheter stock is processed through a plastic extruder whereby a finish coat of an elastomer is applied to a uniform diameter.

Claims 1 and 3-11 are in Condition for Allowance:

Independent claim 1 recites a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member carried on the flexible tubular member, and first and second outer coatings covering the coil reinforcement member, the first coating being softer than the second coating. The elongate flexible tubular member defines a lumen of the catheter and has a first end

defining a proximal end of the catheter and a second end defining a distal end of the catheter. The continuous coil reinforcement member is carried on the elongate flexible tubular member and extends from the proximal end of the catheter to the distal end of the catheter. The first outer coating covers the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter. The second flexible outer coating covers a first portion of the first outer coating between a first transition area of the catheter and the proximal end of the catheter. The second portion of the first outer coating is uncovered by the second outer coating and defines a flexible distal tip of the catheter.

It is respectfully submitted that the prior art of record does not teach or suggest such a construction. More particularly, in the primary reference cited by the Examiner, namely the Stevens '143 patent, it is respectfully submitted that there is no teaching of first and second continuous flexible coatings covering a coil reinforcement member with the outer coating being harder than the inner coating. At best, in the Stevens '143 patent, the extruded thin coat is meant simply to adhere the braided steel reinforcement member onto the underlying tubular body. In addition to the above, nowhere in the Stevens '143 patent is there a teaching that the hardness of the bonding layer relative to the outer coating is of any significance. Still further, in the Stevens '143 patent, a portion of the stainless steel reinforcement member is ground away prior to the application of the single outer flexible coating. Thus, the reinforcement member in the prior art does not extend fully between the proximal end of the catheter and the distal end of the catheter.

The above limitations are clearly recited in independent claim 1 as amended above. For at least these reasons, it is respectfully submitted that independent claim 1 and claims 3-11 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 24 and 26-28 are in Condition for Allowance:

Independent claim 24 recites a reinforced catheter stock for manufacturing reinforced catheters. The catheter stock comprises a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the

tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock; a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and, a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

Again, it is respectfully submitted that the art of record does not teach or suggest a catheter stock for making a reinforced catheter having a continuous coil reinforcement member extending from one end of the catheter to the opposite end and having first and second outer coatings of first and second materials, respectfully, covering the coil reinforcement member wherein the outer coating is harder than the inner coating and a portion of the outer coating being selectively removable from the inner coating to expose a soft distal tip portion of the catheter.

For at least the above reasons, it is respectfully submitted that independent claim 24 as amended above and claims 26-28 dependent therefrom are patentable distinct and unobvious over the art of record.

Claims 41-51 are in Condition for Allowance:

Independent claim 41 recites a reinforced catheter comprising a elongate flexible tubular member, a first outer coating covering the tubular member, a second flexible outer coating covering a first portion of the first outer coating, and a coil reinforcement member carried on the elongate flexible tubular member and disposed at a distal tip of the catheter. The elongate flexible tubular member defines the lumen of the catheter and includes a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. The first flexible outer coating covers the tubular member from the proximal end of the catheter to the distal end of the catheter. The second flexible outer coating covers a first portion of

the first outer coating while a second portion of the first outer coating remains or is otherwise uncovered by the second outer coating and defines a flexible distal tip of the catheter. In claim 41, the first coating is softer than the second coating.

As noted above in connection with the prior art cited by the Examiner, U.S. Patent No. 5,972,143 to Stevens teaches a catheter including a coiled reinforcement member covered in a practical sense by only a single flexible outer coating. The coil reinforcement does not extend the entire length of the catheter but, however, is removed from a distal tip portion thereof.

Independent claim 41 recites a catheter having a coil reinforcement member disposed at a distal tip portion thereof. This is, of course, contrary to the teachings of the Stevens '143 patent which, as noted above, includes a coil reinforcement member in a portion of the catheter but not in the distal tip portion thereof.

For at least the above reasons, applicant respectfully submits that independent claim 41 and claims 42-51 dependent therefrom are patentably distinct and unobvious over the art of record.

The "Supplemental to Interview Summary" is Inadequate:

Applicant's representative respectfully requested a clarification to the Office Action mailed December 3, 2004. During the telephonic interview mistakes by the Office were noted and a clarification was requested, preferably in the form of a new Office Action with a restarted period for response, or a Notice of Allowance. Despite assurances, however, the Examiner has failed to clarify the record in any real way.

More particularly, the "Supplemental to Interview Summary" incorrectly identifies the claims pending in the application. Claims 41-51 were added in the Amendment A filed on September 10, 2004 and dated September 7, 2004. A copy of that Amendment A together with a copy of a transmittal sheet showing three (3) independent claims and a total of twenty-five (25) claims is included for the Examiner's convenience. As can be seen clearly from the record, claims 41-51 are pending in this application yet they were not examined by the Examiner.

However, the Office Action mailed on December 3, 2004 was a simple word processing response to the efforts applicant and his representative made in attempting to advance this application to issuance through diligent prosecution. As can be seen from the record, the Examiner simply used a "copy and paste" function of his word processor as an answer to the Amendment A by copying directly portions of the initial Office Action mailed on June 4, 2004.

Applicant and his representative respectfully request cooperation from the Examiner in the form of a new Office Action which, at a minimum, correctly identifies the claims pending in the application. Also, an Office Action which is not self-contradictory would be appreciated as well.

The Office Action of December 3, 2004 did include a small new work product contribution from the Examiner in the form of a "Response to Arguments" paragraph which is appreciated. However, the Examiner takes the position in that paragraph that "features upon which the applicant relies (i.e., the reinforcement member in the prior art does not extend fully between the proximal and distal ends of the catheter) are not recited in the rejected claims". Applicant respectfully requests that the Examiner carefully read the pending claims.

More particularly, independent claim 1 recites a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the proximal end of the catheter to the distal end of the catheter.

Further, independent claim 24, which is believed to be allowed, recites a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock.

At least independent claims 1 and 24 recite the feature which the Examiner took the position was not recited in the rejected claims.

Next in paragraph at the end of the Office Action, the Examiner stated in the record that "[i]t is the Examiner's position that the reinforcement extends in sections from the proximal end to the distal end." Applicant's representative did not understand this at all. Accordingly, it is respectfully requested that the Examiner prepare a clarification to the previous Office Action or forward a notification of allowance of the pending claims as soon as possible.

Conclusion

In view of the comments and arguments presented above, applicant respectfully submits that all pending claims are in condition for allowance.

Allowance of all pending claims and early notice to that effect is respectfully requested.

Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP

23FEB05
Date

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Certificate of Mailing

Under 37 C.F.R. § 1.8, I certify that this **First Response to After Final Rejection** is being

☐ deposited with the United States Postal Service as First Class mail, addressed to: MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

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Express Mail Label No.:	Signature
Date **February 23, 2005**	Printed Name **Barbara Brazier**

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	STEVENS
For	:	**REINFORCED CATHETER DEVICE, CATHETER STOCK, AND METHODS AND APPARATUS FOR MAKING SAME**
Serial No.	:	10/075,053
Filing Date	:	February 13, 2002
Confirmation No.	:	8092
Examiner	:	Kevin C. Simons
Art Unit	:	3763
Last Office Action	:	December 3, 2004
Attorney Docket No.	:	RSTZ 2 00011-3
		Cleveland, Ohio 44114-2518

STATEMENT OF SUBSTANCE OF INTERVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

A telephonic interview was conducted in connection with the above-identified patent application on February 7, 2005. The substance of that interview is as follows:

Brief Description of the Nature of Any Exhibit Shown or Any Demonstration Conducted:

None

Identification of the Claims Discussed:

Claims 1-51 were discussed.

Identification of the Specific Prior Art Discussed:

A brief discussion of prior art U.S. Patent No. 5,972,143 to Stevens was discussed.

Identification of the Principal Proposed Amendments of a Substantive Nature Discussed, Unless these are Already Described on the Interview Summary Form Completed by the Examiner:

No amendments of a substantive nature were discussed.

Brief Identification of the General Thrust of the Principal Arguments Presented to the Examiner:

The prior art catheter taught in the Stevens '143 patent includes a reinforcement wire braid in a portion of the catheter. Braided and non-braided sections of the catheter are formed wherein a tip portion of the catheter is non-braided. In a first set of claims in the present application, a reinforcement member extends from the proximal end of the catheter to the distal end of the catheter. In another set of claims, a coil reinforcement member is disposed at a distal tip end of the catheter.

General Indication of any other Pertinent Matters Discussed:

Applicant's representative discussed mistakes made by the Examiner in the Office Action Summary Sheet as well as in the body of the Office Action mailed on December 3, 2004. Particularly, it was noted by applicant's representative that many of the claims rejected under 35 U.S.C. § 102 were previously canceled or were otherwise withdrawn from the application. In addition, in one part of the detailed Action, independent claim 24 was indicated by the Examiner as being rejected under 35 U.S.C. § 102 and, in another portion of the Action was indicated by the Examiner as being allowed. Applicant's representative explained to the Examiner that the errors introduced into the record by the Examiner made a response difficult, if not impossible because in part by the Examiner's self-contradictory statements. The Examiner promised a clarification. However, applicant's representative is still waiting for a complete clarification.

General Results or Outcome of the Interview:

Examiner tendered a "Supplemental to Interview Summary" sheet which only partially clarified the record. More particularly, the detailed comments presented by the Examiner in the Office Action mailed December 3, 2004 still includes self-contradictory positions and pending claims remain misidentified.

Respectfully submitted,

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Under 37 C.F.R. § 1.8, I certify that this **Statement of Substance of Interview** is being

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Express Mail Label No.:	**Signature**
Date **February 23, 2005**	**Printed Name** **Barbara Brazier**

Attorney Docket No.: RSTZ 2 00011

AMENDMENT TRANSMITTAL LETTER

Ser. No.: 10/075,053	Filed: February 13, 2002	Examiner: Kevin C. Sirmons
Art Unit: 3763	Title: REINFORCED CATHETER DEVICE, CATHETER STOCK, AND METHODS AND APPARATUS FOR MAKING SAME	

To the Commissioner for Patents:

Transmitted herewith is an *Amendment* in the above-identified application. The fee has been calculated as shown below.

CLAIMS REMAINING				
(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
TOTAL CLAIMS (37 CFR 1.16(c))	25 - 40 =	0	x $ 18	= $0.00
INDEPENDENT CLAIMS (37 CFR 1.16(b))	3 - 5 =	0	x $ 86	= $0.00
			TOTAL =	$ 0.00

☒ No additional fee is required.
☐ A check in the amount of $ is attached.
☐ Charge $ to Deposit Account No. 06-0308.
☐ Applicants hereby petition the Commissioner under 37 C.F.R. § 1.136(a) and request a **month extension of time** to respond to the outstanding Office Action. Enclosed is a check in the amount of $ .00 to cover the applicable extension of time fees.
☒ Applicants request any extensions of time that may be necessary and authorize the required fees be charged to Deposit Account No. 06-0308.
☒ Please charge any additional fees or credit overpayment to Deposit Account No. 06-0308.

Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & MCKEE, LLP

07 SEP 04
Date

Michael E. Hudzinski, Reg. No. 34,185
1100 Superior Avenue, Seventh Floor
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216/861-5582

CERTIFICATE OF MAILING

I certify that this Amendment Transmittal Letter and accompanying document(s) are being
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☐ deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated below and is addressed to: MAIL STOP AMENDMENT, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Express Mail Label No.:	Signature
	Barbara Brazier
Date	Printed Name
September 7, 2004	Barbara Brazier

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	STEVENS
For	:	**REINFORCED CATHETER DEVICE, CATHETER STOCK, AND METHODS AND APPARATUS FOR MAKING SAME**
Serial No.	:	10/075,053
Filing Date	:	February 13, 2002
Confirmation No.	:	8092
Examiner	:	Kevin C. Sirmons
Art Unit	:	3763
Last Office Action	:	June 4, 2004
Attorney Docket No.	:	RSTZ 2 00011-3

Cleveland, Ohio 44114-2518

AMENDMENT A

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action of June 4, 2004, please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 13 of this paper.

Amendments to the Specification:

Please replace the paragraph beginning on page 13 at line 31 with the following amended paragraph:

After the finish coated catheter stock **64** is formed in step **43**, the tube is cut or divided in step **44** at selected locations to produce individual reinforced catheters **66** (Fig. 4a) having the length and other properties desired. Using this method, each individual reinforced catheter has an inner wall formed by the PTFE material **51**, a wire reinforcement member **54**, an intermediate portion formed by a relatively soft, e.g. 40D, material **58** (first flexible outer coating), and an outer wall portion formed by the relatively hard, e.g. 70D, finish coating **62** (second flexible outer coating).

Please replace the paragraph beginning on page 14 at line 22 with the following amended paragraph:

The preferred embodiment of the reinforced catheter **68** produced after the grinding step is shown in Figure 4b. The catheter has a first end **67** and a second end **69**. The ground end of the reinforced catheter **68** defines a flexible distal (second) portion **72**, ~~and~~ an opposite relatively less flexible proximal (first) portion **74**, and a first transition area **73** therebetween. The distal (second) portion **72** of each catheter **68** is selectively ground to a reduced diameter relative to the proximal (first) portion **74** or main body portion to provide the desired flexibility of the catheter **68** (step **46**). The grinding operation is selectively a one of a step grinding operation or a smooth long taper grinding operation.

Amendments to the Claims:

Listing of Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

1. (Currently Amended) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a continuous coil reinforcement member carried on the elongate flexible tubular member and extending ~~between~~ from the proximal end of the catheter ~~and~~ to the distal end of the catheter;

a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter; and,

a second flexible outer coating covering a first portion of the first outer coating between a first transition area of the catheter and said proximal end of the catheter, a second portion of the first outer coating being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating.

2. (Canceled)

3. (Currently Amended) The reinforced catheter according to claim ~~2~~ 1 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

4. (Original) The reinforced catheter according to claim 1, further comprising a marker band disposed adjacent the distal end of the catheter on the outer coating.

5. (Original) The reinforced catheter according to claim 4, wherein the marker band is formed of a one of gold material and platinum material.

6. (Original) The reinforced catheter according to claim 1, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

7. (Original) The reinforced catheter according to claim 1, wherein the continuous coil reinforcement member is a stainless steel wire.

8. (Original) The reinforced catheter according to claim 1, wherein the continuous coil reinforcement member defines a helical pattern.

9. (Original) The reinforced catheter according to claim 1, wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

10. (Original) The reinforced catheter according to claim 1, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

11. (Original) The reinforced catheter according to claim 1, wherein the second outer coating is comprised of a nylon material.

12. (Withdrawn) A method of manufacturing multiple reinforced catheters comprising the steps of:

providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members;

providing a selected length of a reinforcement wire;

for substantially the length of the cylindrical tube, advancing the cylindrical tube from the first spool member to the second spool member while simultaneously wrapping the reinforcement wire onto said portion of the cylindrical tube between the first and second spool members to form a continuous length of reinforced catheter stock;

coating the reinforced catheter stock with a predetermined thickness of a first coating and followed by a second coating harder than said first coating for substantially the length of the cylindrical tube to form a continuous length of coated catheter stock; and,

cutting the coated catheter stock at selected locations corresponding to desired catheter lengths to form a plurality of reinforced catheters.

13. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12 further including the step of grinding the second coating of any one or more of said plurality of reinforced catheters to expose a portion of the first coating and to provide a desired outer surface finish and a desired flexibility along the longitudinal length of the catheter.

14. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 13 further including the step of swaging a marker band around the outer surface of the coating at a distal end of the any one or more of said plurality of reinforced catheters.

15. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 14, wherein the step of swaging the marker band includes swaging a marker band formed of one of a group of materials consisting of gold and platinum.

16. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 14, wherein the grinding step includes grinding a portion of the catheter beginning at a first end defining a distal end of the catheter for a predetermined distance along the longitudinal length of the catheter toward a second end defining a proximate end of the catheter.

17. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 16, wherein the grinding step includes grinding the portion of the catheter such that the thickness of the finish coating at the distal end of the catheter is less than the thickness of the finish coating at the proximate end of the catheter.

18. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 17, further including the step of coating a ground portion of the catheter with a predetermined thickness of a soft finish coating.

19. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 18, wherein the step of coating the ground portion with said soft finish coating includes coating the ground portion with a urethane material.

20. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the cylindrical tube is a polytetrafluoroethylene (PTFE) material.

21. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the reinforcement wire is a stainless steel wire.

22. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the wrapping step includes wrapping said reinforcement wire onto said cylindrical tube in a helical pattern.

23. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the coating step includes coating the reinforced catheter stock with a predetermined thickness of said first coating followed by a predetermined thickness of said second coating, the first coating having a Shore hardness of about 40D and said second coating having a Shore hardness of about 70D.

24. (Currently Amended) A reinforced catheter stock for manufacturing reinforced catheters, the catheter stock comprising:

a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock; ~~and~~

a continuous coil reinforcement member carried on the elongate flexible tubular member and extending ~~between~~ from the lead end of the catheter stock ~~and~~ to the trailing end of the catheter stock;

a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and,

a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

25. (Canceled)

26. (Currently Amended) The reinforced catheter stock according to claim ~~25~~ 24, wherein:

the continuous coil reinforcement member defines a helical pattern;

the first material has a Shore hardness of about 40D; and,

the second material has a Shore hardness of about 70D.

27. (Original) The reinforced catheter stock according to claim 24, wherein the elongate flexible tubular member is a polytetrafluoroethylene (PTFE) material.

28. (Original) The reinforced catheter stock according to claim 24, wherein the continuous coil reinforcement member is a stainless steel wire.

29. (Withdrawn) A method of manufacturing a reinforced catheter stock, the method comprising the steps of:

providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members;

providing a selected length of a reinforcement wire; and

while advancing the cylindrical tube from the first spool member to the second spool member, wrapping the reinforcement wire onto the cylindrical tube at a point between the first and second spool members for substantially the length of the cylindrical tube to form a continuous length of reinforced catheter stock.

30. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 27, further comprising the step of coating the reinforced catheter stock with a predetermined thickness of a first finish coating then a second finish coating harder than said first finish coating for substantially the length of the cylindrical tube to form a continuous length of coated catheter stock.

31. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the step of providing said elongate cylindrical tube includes providing a polytetrafluoroethylene (PTFE) material.

32. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the step of providing said selected length of said reinforcement wire includes providing stainless steel wire.

33. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the wrapping step includes wrapping said reinforcement wire onto said cylindrical tube in a helical form.

34. (Withdrawn) An apparatus for manufacturing reinforced catheter stock, the apparatus comprising:

a first support member and a second support member, the first and second support members being spaced apart and carrying an elongate cylindrical tube with a portion of the cylindrical tube extending between the first support member and the second support member;

a winder device carrying a selected length of a reinforcement member, the winder device being adapted to wind the reinforcement member onto the cylindrical tube at a point between the first and second support members; and,

a control device simultaneously controlling i) advancement of the cylindrical tube relative to the winder device and ii) winding the reinforcement member onto said cylindrical tube by the winder device at the point between the first and second support members.

35. (Withdrawn) The apparatus according to claim 34, wherein said first support member includes a pay-out spool and said second support member includes a take-up spool, the pay-out spool and the take-up spool being responsive to the control device to pay out the elongate cylindrical tube from the pay-out spool and onto the take-up spool.

36. (Withdrawn) The apparatus according to claim 34, wherein the elongate cylindrical tube is a polytetrafluoroethylene (PTFE) material.

37. (Withdrawn) The apparatus according to claim 34, wherein the winder device includes:

a coiler tip member defining i) a central bore adapted to receive said cylindrical tube at the point between the pair of spaced apart support members, and ii) an offset opening carrying said reinforcement member, the coiler tip member

being selectively rotatable relative to said cylindrical tube to wind the reinforcement member onto the cylindrical tube at selected varied angles relative to a plane perpendicular to a longitudinal axis of the cylindrical tube.

38. (Withdrawn) The apparatus according to claim 37, wherein the winder device further includes:

a motor for rotating the coiler tip member relative to the cylindrical tube;

a spool for carrying the reinforcement member; and,

a tubular member adapted to rotate with the coiler tip member to feed the reinforcement member from said spool and through the offset opening of the coiler tip member as the reinforcement member is wound onto the cylindrical tube.

39. (Withdrawn) The apparatus according to claim 38, wherein the winder device is adapted to wind the reinforcement member onto the cylindrical tube in a helical pattern.

40. (Withdrawn) The apparatus according to claim 34, wherein the reinforcement member is comprised of a stainless steel wire.

41. (New) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a first flexible outer coating covering the tubular member from the proximal end of the catheter to the distal end of the catheter;

a second flexible outer coating covering a first portion of the first outer coating, a second portion of the first outer coating being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating; and,

a coil reinforcement member carried on the elongate flexible tubular member and disposed at said distal tip of the catheter.

42. (New) The reinforced catheter according to claim 41, wherein said coil reinforcement member is carried on said tubular member from said distal end of the catheter to said proximal end of the catheter.

43. (New) The reinforced catheter according to claim 42 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

44. (New) The reinforced catheter according to claim 41, further comprising a marker band disposed adjacent the distal end of the catheter on the outer coating.

45. (New) The reinforced catheter according to claim 44, wherein the marker band is formed of a one of gold material and platinum material.

46. (Original) The reinforced catheter according to claim 41, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

47. (Original) The reinforced catheter according to claim 41, wherein the continuous coil reinforcement member is a stainless steel wire.

48. (Original) The reinforced catheter according to claim 41, wherein the continuous coil reinforcement member defines a helical pattern.

49. (Original) The reinforced catheter according to claim 41, wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

50. (Original) The reinforced catheter according to claim 41, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

51. (Original) The reinforced catheter according to claim 41, wherein the second outer coating is comprised of a nylon material.

Remarks

This Amendment is responsive to the Office Action mailed June 4, 2004, in connection with the above-identified patent application. In that Action, the drawings were objected to because, according to the Examiner, they did not include several reference sign(s) mentioned in the description. The same objections were applied to the specification by the Examiner.

Claims 1-11 and 24-28 are pending in this application. Among them, claims 1, 2, 6-11, 24, 25, 27, and 28 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,972,143 to Stevens. Claims 3 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens. Claim 4 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,147,315 to Weber. Lastly, claim 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of Weber and further in view of U.S. Patent No. 5,843,051 to Adams, et al.

THE NON-ART MATTERS

As noted above, the drawings were objected to because, according to the Examiner, they do not include several reference sign(s) mentioned in the description. The drawings were objected to as failing to comply with 37 C.F.R. § 1.84(p)(5). The Examiner required a proposed drawing correction or corrected drawings because, according to him, they do not include reference sign(s) for: a first end, a second end; a first flexible outer coating; a second flexible outer coating; a first portion; a first transition area and a second portion. The Examiner further noticed that the same objections apply to the specification.

The Drawings are in Proper Form:

Applicant has tendered a proposed drawing correction to Figure 4b in an attached Request for Amendment to the Drawings. In that drawing correction, the first and second ends of the subject catheter are identified. The first and second flexible outer coatings have already been identified at reference numerals 58 and 62, respectively. The first portion of the catheter is identified in the drawing figures at reference numeral 74 and the second portion of the catheter is identified in the

drawing figures at reference numeral 72. Reference numeral 73 has been added to identify the first transition area between the first and second portions of the catheter.

It is respectfully submitted that no new matter has been added. Support is found in the specification as originally filed at least in the areas beginning on page 4 at line 19 and in the claims.

The Specification is in Proper Form:

Applicant has tendered an amendment to page 14 of the specification to place it in better conformance with the drawing figures as amended.

It is respectfully submitted that no new matter has been added. More particularly, support is found for the changes to the specification tendered above in the specification and claims as originally filed and, particularly, beginning at page 4, line 19 and in the claims.

For at least the above reasons, it is respectfully submitted that the specification is in proper form.

THE ART REJECTIONS

As noted above, claims 1, 2, 6-11, 24, 25, 27, and 28 were rejected as being anticipated by Stevens. Claims 3 and 26 were rejected as being unpatentable over Stevens. Claim 4 was rejected as being unpatentable over Stevens in view of Weber. Lastly, claim 5 was rejected as being unpatentable over Stevens in view of Adams, et al.

The Present Application:

For purposes of review, the subject application is directed to a reinforced catheter device including a coil reinforcement member carried on an inner tubular member, the coil reinforcement member being layered by first and second flexible outer coatings. The continuous coil reinforcement member is carried on the elongate flexible tubular member and extends from the proximal end of the catheter to the distal end of the catheter. First and second continuous flexible coatings cover the coil reinforcement member and the tubular member in an overlapping fashion substantially entirely between the proximal end of the catheter and the distal end of

the catheter. The outer coating is harder than the inner coating and is selectively removed over a length of the catheter to provide a thin flexible tip portion of the catheter. As described in the specification, the coil reinforcement member is disposed in the flexible tip portion as well as in the main body or proximal end of the catheter.

U.S. Patent No. 5,972,143 to Stevens:

U.S. Patent No. 5,972,143 to Stevens teaches a catheter including a coil reinforcement member covered in a practical sense by only a single flexible outer coating. In addition, the coil reinforcement member does not extend the entire end of the catheter but, however, is removed from a distal tip portion therein.

As described in the Stevens '143 patent, a braided overlay is adhered to an inner tubular member using a suitable bonding agent such as a UV curable epoxy coating. It is suggested at the top of column 7 of the '143 patent that a urethane or a nylon material can be used as a bonding agent.

After the reinforcement wire is braided onto the underlying tubular member, a thin secondary plastic coating is applied. It penetrates between the strands of wire braid and mechanically locks the stainless steel wires in place so that they do not unravel during a subsequent grinding operation intended to remove portions of the braided reinforcement wire along the length of the catheter. After the braid has been removed in selected areas (distal tip portion), the braided and non-braided continuous section of catheter stock is processed through a plastic extruder whereby a finish coat of an elastomer is applied to a uniform diameter.

Claims 1 and 3-11 are in Condition for Allowance:

Independent claim 1 recites a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member carried on the flexible tubular member, and first and second outer coatings covering the coil reinforcement member, the first coating being softer than the second coating. The elongate flexible tubular member defines a lumen of the catheter and has a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. The continuous coil reinforcement member is carried on the elongate

flexible tubular member and extends from the proximal end of the catheter to the distal end of the catheter. The first outer coating covers the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter. The second flexible outer coating covers a first portion of the first outer coating between a first transition area of the catheter and the proximal end of the catheter. The second portion of the first outer coating is uncovered by the second outer coating and defines a flexible distal tip of the catheter.

It is respectfully submitted that the prior art of record does not teach or suggest such a construction. More particularly, in the primary reference cited by the Examiner, namely the Stevens '143 patent, it is respectfully submitted that there is no teaching of first and second continuous flexible coatings covering a coil reinforcement member with the outer coating being harder than the inner coating. At best, in the Stevens '143 patent, the extruded thin coat is meant simply to adhere the braided steel reinforcement member onto the underlying tubular body. In addition to the above, nowhere in the Stevens '143 patent is there a teaching that the hardness of the bonding layer relative to the outer coating is of any significance. Still further, in the Stevens '143 patent, a portion of the stainless steel reinforcement member is ground away prior to the application of the single outer flexible coating. Thus, the reinforcement member in the prior art does not extend fully between the proximal end of the catheter and the distal end of the catheter.

The above limitations are clearly recited in independent claim 1 as amended above. For at least these reasons, it is respectfully submitted that independent claim 1 and claims 3-11 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 24-28 are in Condition for Allowance:

Independent claim 24 recites a reinforced catheter stock for manufacturing reinforced catheters. The catheter stock comprises a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock; a continuous coil

reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and, a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

Again, it is respectfully submitted that the art of record does not teach or suggest a catheter stock for making a reinforced catheter having a continuous coil reinforcement member extending from one end of the catheter to the opposite end and having first and second outer coatings of first and second materials, respectfully, covering the coil reinforcement member wherein the outer coating is harder than the inner coating and a portion of the outer coating being selectively removable from the inner coating to expose a soft distal tip portion of the catheter.

For at least the above reasons, it is respectfully submitted that independent claim 24 as amended above and claims 26-28 dependent therefrom are patentable distinct and unobvious over the art of record.

Conclusion

In view of the comments and arguments presented above, applicant respectfully submits that all pending claims are in condition for allowance.

Allowance of all pending claims and early notice to that effect is respectfully requested.

Respectfully submitted,

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07SEP04
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Certificate of Mailing

Under 37 C.F.R. § 1.8, I certify that this **Amendment A** is being

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	Barbara Brazler
Date	**Printed Name**
September 7, 2004	**Barbara Brazler**